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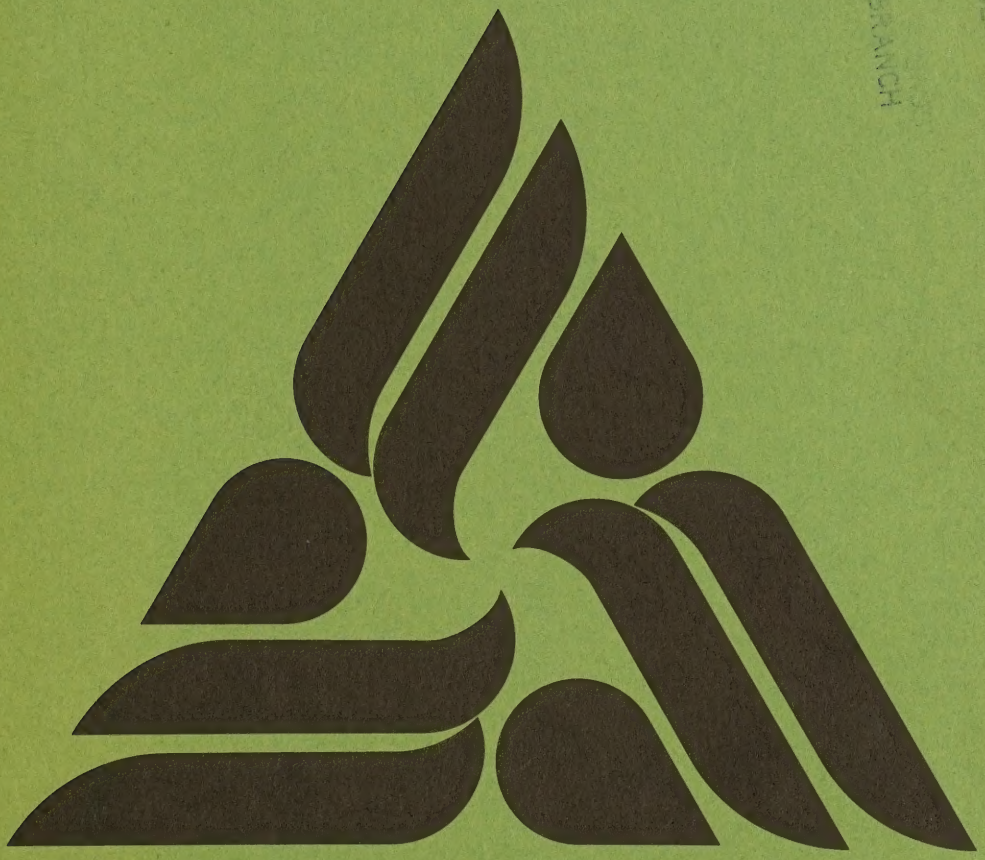
November 26, 1990



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U.S. DEPARTMENT OF AGRICULTURE
AGRICULTURAL BIOTECHNOLOGY RESEARCH ADVISORY COMMITTEE
MINUTES OF MEETING
November 26-27, 1990

November 26, 1990

CALL TO ORDER AND APPROVAL OF AGENDA AND MINUTES

Dr. Bennie Osburn, Chair, convened the ninth meeting of the Agricultural Biotechnology Research Advisory Committee (ABRAC) on November 26, 1990, in the Mills House Hotel in Charleston, South Carolina. The meeting was open to the public.

Members present included:

Bennie Osburn, Chair, University of California, Davis, CA;
William Witt, Food and Drug Administration, National Center for Toxicological Research, Jefferson, AR;
Hugh Bollinger, TerraTek, Inc., Salt Lake City, UT
Frank Whitmore, Ohio State University, Wooster, OH;
John Kemp, New Mexico State University, Las Cruces, NM;
Sue Tolin, Virginia Polytechnic Institute and State University, Blacksburg VA;
Edward Korwek, Hogan and Hartson, Washington, DC;
George Hill, Meharry Medical College, Nashville, TN;
David Andow, University of Minnesota, St. Paul, MN;
Anne Vidaver, University of Nebraska, Lincoln, NE;
David Kline, State University of New York, New Paltz, NY
Alvin Young, Executive Secretary and Director, USDA Office of Agricultural Biotechnology, Washington, DC.

Dr. Osburn welcomed members, staff, and guests. He noted that three members were absent -- Dr. Bulla, Dr. Hafs and Dr. Letourneau. Dr. Osburn welcomed and introduced Dr. Hugh Bollinger who was attending his first ABRAC meeting.

Dr. Osburn called for additions or corrections to the agenda. None were voiced and the agenda was approved as distributed.

Dr. Alvin Young, Director, USDA Office of Agricultural Biotechnology (OAB), introduced the OAB staff members present and asked the visitors present to identify themselves (Appendix A).

Dr. Osburn invited additions or corrections to the minutes of the ABRAC meeting of April 23-24, 1990.

Dr. David Andow asked that the last sentence of paragraph three on page 21 be amended to clarify that ABRAC regarded the draft USDA Research Guidelines for Planned Introduction into the Environment of Organisms with Modified Heritable Traits (henceforth referred to as the Guidelines) as acceptable for the proposed action of beginning the Environmental Impact Statement (EIS) process, and had not approved the entire document.

Dr. Sue Tolin commented that the minutes were improved and more accurate. She said there were still a few minor corrections and additions to be made, such as the identification of resolutions and the addition of appropriate documents as appendices. She said she would give other minor corrections to OAB for inclusion.

With these corrections and additions, the April 23-24, 1990 minutes were approved unanimously.

Dr. Osburn then asked the committee to consider the minutes of the June 21-22, 1990 ABRAC meeting.

Dr. Andow noted a number of substantive changes. At the beginning of page six, Dr. Andow said the minutes should reflect that he asked for a sense of the Committee on participation in the EIS, rather than on "structural aspects of the EIS effort." On page six, paragraph five, he asked that the final sentence be amended to read "recognizing the difficulties OAB had in scheduling a scoping session in the Corn Belt, Dr. Andow underlined the importance of holding a scoping session in the Corn Belt."

On page eight Dr. Andow asked that the word "non-transgenic" be put in quotation marks throughout the discussion of the Food Safety Inspection Service (FSIS) proposed process. On page 13, paragraph 4, he asked that the minutes show that other Committee members agreed with Dr. Whitmore that the FSIS approach is far-sighted. On page 13, paragraph 12, he asked that the wording be amended to read that Dr. Andow asked that the motion be voted on again, so that it would be clear that the motion indicates support for the process FSIS is using.

On page 18, paragraph 14, Dr. Andow noted that Dr. MacKenzie asked the group to review the analysis of the nominal group technique discussion of the Guidelines, but no document had been forwarded to ABRAC members for their review.

Referring to page 19, paragraph 3, Dr. Andow asked for the Committee's advice about what to do with Dr. Kemp's statement that the "ABRAC is already on record as supporting the guidelines," noting that this is not entirely correct. Dr. Kemp and Dr. Osburn replied that the ABRAC had gone on record, in meetings prior to the April, 1990 meeting, as supporting the Guidelines. Dr. Andow requested that the phrase be amended to clarify that previous ABRAC committees had supported the Guidelines. Dr. Kemp agreed.

With these changes, the June 21-22, 1990 minutes were approved unanimously.

SUMMARY OF GUIDELINES-RELATED ACTIVITIES SINCE THE LAST MEETING

Dr. Young reported that since the last meeting, OAB had forwarded the draft research guidelines to Dr. Charles E. Hess, Assistant Secretary for Science and Education, to begin the EIS process. He said that Dr. Hess, after discussion with representatives of member agencies of the U.S. Department of Agriculture (USDA) Committee on Biotechnology in Agriculture (CBA), decided not to pursue the EIS because it would delay the completion of the guidelines for two years.

Dr. Hess then began to study ways of promulgating the guidelines sooner. The USDA Office of the General Counsel (OGC) recommended that the guidelines could be tied to USDA agencies through their National Environmental Policy Act (NEPA) procedures. At this point Dr. Hess sent a letter to ABRAC members summarizing the change in approach.

Dr. Young explained that the OAB staff had amended the guidelines to reflect this change in approach, and had presented the amended version at a series of public meetings. However, the Council on Environment Quality (CEQ) and the Office of Management and Budget (OMB) questioned the new approach and pointed out potential problems in using the guidelines as part of the NEPA process. Consequently, the guidelines were revised again, divorcing them from NEPA.

Dr. Young stated that the OAB experience in preparing an Environmental Assessment (EA) on the transgenic fish experiment, had confirmed that it would be difficult to use the guidelines for NEPA purposes.

Dr. Young reported that Dr. Hess had decided to split the guidelines into two parts -- principles and an implementation phase. USDA would proceed to publish the first part immediately in the Federal Register for public comment, along with the confinement practices, and remove references to implementation. A second document would deal with implementation. USDA is now discussing the issue of scope and other aspects of the guidelines with OMB.

Dr. Young concluded by noting that this daily evolution has made it difficult to keep the ABRAC informed and he expressed regret that ABRAC members have not seen the final draft of the guidelines.

Ms. Maryln Cordle said that OMB is reviewing the guidelines in terms of overall policy implications and how the document fits into other agricultural programs. She said it will take time to come to agreement with OMB.

Dr. Young informed the ABRAC that the Biotechnology Science Coordinating Committee (BSCC) has been dissolved and a new committee established to deal primarily with research issues. For policy issues, Dr. Young indicated that legislation passed in 1989 established a National Biotechnology Policy Board (NBPB) which met recently. Staff support for the NBPB is being provided by the National Institutes of Health (NIH) and Dr. Hess is the USDA representative to the NBPB. Ms. Cordle pointed out that the Council on Competitiveness, chaired by the Vice President, remains the focal point for overall Federal policy on biotechnology.

Dr. Bollinger asked how the Competitiveness Council views ABRAC and the guidelines? Dr. Young responded that Ms. Cordle had briefed the Competitiveness Council on the guidelines. Ms. Cordle said that OMB would be looking to the Competitiveness Council for advice. She added that OMB wished to avoid disrupting current administration policies on oversight of biotechnology.

Dr. Osburn asked who sits on the Competitiveness Council? Ms. Cordle responded that Secretary Yeutter sits on the Competitiveness Council and Dr. Hess sits on the Working Group on Biotechnology. Dr. Young added that Dr. Hess is tied into all three of these policy setting groups.

Dr. Sorensen asked what tone OMB wanted to set in the guidelines. Ms. Cordle answered that the administration does not want to give the impression that biotechnology is very different from traditional methods of genetic modification.

Dr. Andow asked for a brief history of why the NBPB was formed. Dr. Young responded that Congress was concerned about the handling of biotechnology issues and wanted to open policy discussions to a wider group than Federal employees. Ms. Cordle added that some members of Congress have expressed concern about the difficulties the Environmental Protection Agency (EPA) has experienced in promulgating regulations on biotechnology.

Dr. Korwek remarked that it seems there is a general lack of support for the Guidelines in the Administration. He said ABRAC may need to make an effort to get the constituencies which support the Guidelines involved.

Dr. Young agreed, noting that we may not see phase two of the process if it becomes too controversial. He added that the public meetings indicate that there is a constituency which wants the Guidelines. He said that the situation is analogous to the constituencies which are supporting the Department's attempt to obtain more money for agricultural research through the National Research Initiative. Thus far, these groups have not been successful in obtaining large increases in funding levels.

Dr. Vidaver asked if the NBPB has decision-making powers. Ms. Cordle said that it is purely advisory.

OAB SUMMARY OF PUBLIC MEETINGS

Mr. Milton Robinson reported that OAB had held a series of public meetings on the Guidelines in September 1990 in Sacramento, California; St. Louis, Missouri; Raleigh, North Carolina; and Washington, D.C. Over 100 people attended. The comments received from the participants are summarized in the background report which is attached as Appendix B.

Mr. Robinson gave the Committee his impressions of the public meetings and of the comments received. Most comments were informal, but the National Wildlife Federation (NWF) submitted written comments for the record during the Washington D.C. meeting. He said OAB had tried to conduct the meeting in a non-threatening manner in order to encourage participation.

Mr. Robinson reported that the 236 comments received could be divided into nine groups as follows:

Twenty one percent of the comments noted that the guidelines needed to be more clear. Some indicated that the purpose needs to be more evident and others that the scope is too complicated. One third of these said that the title doesn't fit small-scale testing and is thus misleading. Some recommended adding a flow chart and improving the definitions. Comments also advocated better examples including confinement.

Twenty percent of the comments expressed concern that jurisdiction between agencies and coordination mechanisms are unclear. Some comments advocated a single set of guidelines for all agencies. There was concern that the burden of paperwork would be increased. Most commenters in this group indicated they would need additional resources to comply.

Fifteen percent commented on the need for a credible system for assuring safety and achieving public confidence. Comments from industry expressed a need for public acceptance. Some said government should provide safety assurances, i.e., a stamp of approval for field testing. Others said the public may be losing confidence in USDA's ability to produce guidelines. Comments indicated that low risk organisms are still covered and there needs to be a mechanism for exclusions. Others indicated that there needs to be a mechanism to encourage public participation.

Eleven percent commented on the role of Institutional Biosafety Committees (IBC). Most said IBC's should have a major role in safety assessments, but they need education, training and guidance.

Ten percent stressed the urgent need for the guidelines to be published and expressed confusion about the lack of progress in moving forward.

A small number of comments addressed compliance with NEPA and asked for a standard outline to assist in compliance.

A small number of comments expressed the view that benefits should be included in assessments and that the guidelines may not adequately define low risk in this context.

Two percent of the comments requested additional explanation regarding the scope of oversight. Four comments dealt with miscellaneous issues.

Dr. Young noted that the public meetings were held with very little advance notice because of delays with the guidelines and the need to complete them before the end of the fiscal year. He said that OAB had mailed out 400-500 copies of the guidelines prior to the meetings, but there had not been enough time to announce the meetings in the Federal Register.

Dr. Korwek asked what position the NWF had taken at the public meeting in Washington D.C. Mr. Robinson responded that NWF had been both supportive and critical. The NWF comments emphasized the need for public involvement and safety assurances. They also were critical of the short notice given about the public meetings.

Dr. Korwek and Dr. Hill asked who supported the guidelines at the public meetings? Mr. Robinson replied that the Farm Bureau, the California Biotechnology Association, and the North Carolina Biotechnology Center had expressed support for the guidelines during the public meetings.

Dr. John Gerber commented that, in his opinion, the meetings went well and were well attended. IBC's were well represented. He complimented Mr. Robinson on his excellent job in conducting the meetings. Dr. Gerber said that, from his perspective as an experiment station assistant director, the land-grant system is ready for the Guidelines. He said there is a clear message from IBC's having responsibility to university administrators to assure safety that they need the guidelines. He said IBC's need training and clear guidance on biosafety issues. Furthermore, although the APHIS system is working well, university researchers may be avoiding field tests because they have limited access to legal counsel. In this way, according to Dr. Gerber, the failure to produce guidelines may be affecting the structure of academic research.

Dr. Marshall Phillips commented on the scientific and confinement issues which surfaced at the meetings. He said there had been very few comments on the scientific aspects, which he interpreted to mean that the science was sound.

However, because people had very little time to study the guidelines prior to the meetings, they may not have had time to study the science in detail. Some of the issues raised were the high costs of doing animal research in containment; the need to pursue high-risk, high-benefit experimental work; and the perception that even low risk field work needed to receive some sort of review in order to reassure the public.

Mr. Robinson, stepping out of his official OAB staff role, offered his personal comments on perceptions of NEPA. He said the reason NEPA is often perceived as a problem by government officials is that they do not understand it. He said some USDA officials view NEPA as an impediment instead of an aid in policy development. He said NEPA is a procedural act which should assist in sound decision making. It requires government officials to explain decisions and consider alternatives. It does not say the government may not undertake certain actions. NEPA also encourages public interaction. Mr. Robinson indicated it is against the law to try to subvert NEPA. In conclusion, he said he is pleased that the Cooperative State Research Service (CSRS) is adopting NEPA regulations and will implement NEPA.

Dr. Gerber added that the compilation of comments had now been sent back to the participants. He said there is an urgent need to promulgate the guidelines. He stated that APHIS may decide to exempt some organisms from its plant pest regulations, and this would leave certain experiments without safety assurances unless the guidelines are in place.

Dr. Osburn thanked the OAB staff their efforts in conducting the public meetings and for the excellent presentations describing the meetings.

Dr. Osburn recalled that he attended the meeting in Sacramento along with Dr. Lee Bulla. The attendees numbered 16-18 people including the Chair of the IBC at Davis and representatives of the California Biotechnology Association, the media, and APHIS. According to Dr. Osburn, the guidelines were accepted as a logical step in the process of agricultural research and development. In his view, university administrators and researchers alike need the guidelines in order to know to how to proceed with this type of research. He said many researchers are reluctant to go to APHIS for a permit. He added that there is strong support for involving IBC's in the oversight process and for having some local control. The role of the IBC's needs to be clarified and he suggested the ABRAC may wish to address this issue. He also said there is a need for exemptions from current regulations in some cases. He added that industry in California did not feel informed about how oversight is developing.

Dr Osburn asked other ABRAC members who had attended the meetings to comment.

Dr. Witt had attended the St. Louis meeting. He complimented Mr. Robinson on his role as facilitator at the meetings. The St. Louis meeting was attended by several IBC members who expressed a strong need for guidelines. Dr. Witt related that IBC members expressed the desire for some local control with enough Federal oversight to relieve pressure on IBC's. He reiterated the need for training stating that current IBC members may not have the expertise needed to review field release proposals. He said several people expressed the need for a flow chart and a standard set of guidelines for all agencies.

Dr. Whitmore had attended the meeting in Raleigh. He said his observations were similar to those already reported. He was surprised by the lack of substantive comments on the guidelines. The discussions at Raleigh, he said, tended to be more philosophical. Drawing upon his experience as an IBC member at Ohio State, he felt that IBC's would become familiar with the guidelines and would be able to advise researchers on how to use them. He said Dr. Ron Sederoff, a former ABRAC member and early contributor to the guidelines, had attended the meeting in Raleigh, and was very pleased with the development of the guidelines.

Dr. Kline also attended the meeting in Raleigh. He said there had been a discussion of weighing risks against benefits, and that some participants had expressed surprise that the guidelines did not contain a discussion of benefits.

Dr. Kemp attended the Washington D.C. meeting. He recalled that Dr. Jane Rissler of the NWF had expressed concern that the scientific principles of the guidelines were being decoupled from implementation. NWF's other concern was the final exclusion of the scope definition. NWF believed it to be too big a loophole, and questioned who will decide what is excluded under this exemption.

Dr. Andow asked if OAB had recorded the disciplines represented at the public meetings. He asked if environmental scientists were present. Mr. Robinson replied that the disciplines of participants were not recorded. His impression was that not many ecologists attended.

Dr. Hill asked if industry representatives offered any special views during the meetings. Dr. Vidaver asked what percentage of participants came from industry? Dr. Gerber replied that approximately 16 percent of the participants were from industry. They wanted a system to provide safety assurances to gain public confidence as well as a clear pathway to commercialization.

Dr. Korwek said he was perplexed about the perception that the public meetings had provided a ringing endorsement of the guidelines. He said the table shows that only 10 percent of 90 comments expressed support for the guidelines. There seemed to

be a few vocal people, but he questioned if this indicates broad support. Of equal importance, he said, is to note who did not attend the meetings. Many associations, he said, were not present including the Ecological Society of America, the American Society of Microbiology, the Industrial Biotechnology Association, and the Association of Biotechnology Companies.

Dr. Whitmore replied that almost everyone present seemed supportive of the guidelines, but they didn't make enthusiastic comments because they believed the guidelines would inevitably be published. They didn't realize the importance of their comments in this regard. Dr. Osburn agreed with Dr. Whitmore's assessment based on his experience at the Sacramento meeting.

Ms. Cordle said the primary concern expressed at the public meetings was not the guidelines per se, but how they will be used. Yet it was difficult for OAB staff and ABRAC members to respond to these concerns because of uncertainties.

Dr. Kemp reminded the Committee that he and Dr. Young had presented the guidelines to a meeting of the American Association for the Advancement of Science in San Antonio, Texas. He said the scientists present didn't raise any problems with the science, but they did have questions about implementation. They also asked how the guidelines could be described as product-driven, when some of the exclusions were based on process.

Dr. Young said this illustrates a problem that may occur if the guidelines are published as principles, that is, people will want to know what is the intended use of the guidelines.

Dr. Gerber disagreed, saying he believed the guidelines will be used even if published as principles.

Mr. Robinson clarified his interpretation of the table. He said 28 people expressed explicit support for the guidelines or 10 percent of 283 comments.

Dr. Korwek said he still does not believe this should be interpreted as support or lack of support. He said the Committee needs to discuss why people didn't attend the meetings. He noted that people said that the Federal system of oversight is the problem, yet ABRAC cannot fix this system. The guidelines cannot provide a uniform system of oversight. He said ABRAC could add a flow chart depicting the system of oversight for the guidelines, but this may be beyond the purview of the committee.

Dr. Tolin followed up on Dr. Kemp's comments and recalled her presentation about the guidelines at the phytopathology meetings. She said people were extremely supportive of the principles. The Organization for Economic Cooperation and Development had used an earlier version of the guidelines as a

background document during its deliberations, and noted that the guidelines were based on very sound scientific principles. Dr. Kemp said he had received similar comments from international experts.

SUMMARY OF PUBLIC COMMENTS ON OSTP SCOPE PRINCIPLES

Ms. Cordle presented a summary of public comments on the Office of Science and Technology Policy (OSTP) scope principles. She reported that on July 31, 1990, OSTP published principles for the scope of oversight for the planned introduction into the environment of organisms with deliberately modified hereditary traits (55 FR 31118), and invited public comment by October 1, 1990. These comments are currently under review by OSTP and Ms. Cordle explained that her presentation was the result of her personal review of the comments received, and not an official response.

Forty four comments were received from 43 different parties. Fourteen were from academia, 17 from industry, 8 from scientific societies, 2 from government, 2 from environmental groups, and 1 from a private consultant.

All comments agreed that risk should determine the need for oversight, and the focus should be on product, not process. Some comments stated that a risk-based policy is long overdue, and that the Coordinated Framework is not entirely risk-based. One comment suggested that the proposed scope definition would close loopholes in the Coordinated Framework.

The majority of comments were supportive of the OSTP scope principles, while offering suggestions for improvement, primarily with regard to the exclusions.

Industry strongly urged that USDA and EPA proceed with proposed guidelines and regulations for public comment, and noted that further delays would be detrimental. Some industry comments suggested that not all small-scale field tests should be regulated and that a notification scheme would be sufficient. However, industry was generally opposed to self regulation. At the same time, industry supported using experience data to develop exclusion categories on a continuing basis.

At least a dozen comments dealt with the issue of flexibility. Some comments thought that flexibility was positive for agency implementation, while others expressed concern that flexibility would lead to continued inconsistencies among agencies.

Many of the comments from academia urged the use of an oversight system similar to the NIH Guidelines, in which the IBC's would play a role in risk assessment with Federal oversight for special cases. Some of these comments urged that a distinction be drawn between oversight of research and oversight for commercial application.

There was no basic disagreement with the general risk evaluation criteria proposed. However, some comments suggested that it be clarified that these are points-to-consider, and that not all information would be necessary in every case. Nearly all the comments supported application of the familiarity and/or similarity concept. All agreed that risk is dependent on the nature of the organisms and the environment. One comment suggested that the criterion of intended use be added.

Almost all the comments agreed that the set "organisms with deliberately modified traits" was broad enough and an appropriate starting point from which exclusions could be identified. Several believed the more familiar term "genetically modified organisms" was preferable. One comment suggested beginning with all organisms.

Many comments stated that all six proposed exclusions were appropriate. However, a small number of comments stated that the exclusions were not risk-based. Nearly everyone agreed that organisms produced by traditional breeding should be excluded. At least one comment stated that the rationale for the exclusions needed to be clarified. Another comment stated that it should be clarified that excluded organisms aren't necessarily exempted from regulation because they may be regulated on a basis other than genetic modification.

Many comments reflected concern about how exclusions four through six would be implemented. Industry generally favored a simple notification scheme to determine if an organisms fell within one of these categories.

Some comments suggested that agencies should develop clear lists of organisms which fall into exclusion six. Others stated that exclusion six is critical and should be required for all agencies.

Some comments stated that exclusions four and five should be subsumed under exclusion six. One comment stated that mutagenesis by transposable elements should be added to exclusion five. Another comment suggested that mutations within a single genome by _in vitro_ mutagenesis, polymerase chain reaction, and homologous recombination should be excluded. Monsanto proposed several exemptions including certain microorganisms with Tn7 or lacZY markers, genetic fusion of _Trichoderma_ strains, and _Agrobacterium_ with a disarmed Ti plasmid configuration.

One comment said that the exclusions for microorganisms didn't reflect reality and experience. Another stated that well characterized non-coding sequences should not be excluded.

Dr. Vidaver asked what would happen now with the OSTP proposal. Ms. Cordle repled that OSTP staff will draft a response

considering the comments. Then a final proposal would be forwarded to the Competitiveness Council for consideration. She said she was not sure of the timeframe.

Dr. Young commented that the scope issue is still not completely resolved. However, he planned to go forward with the guidelines without waiting for a final resolution. Ms. Cordle added that OMB may be concerned that if the guidelines adopt a specific scope, that this will reopen the scope discussion within the Administration. She said the comments on scope need to be fully analyzed.

COMMITTEE DISCUSSION OF PUBLIC MEETINGS AND COMMENTS ON THE GUIDELINES

Dr. Osburn asked for further comments on the public meetings and the Guidelines.

Dr. Andow said that it would be useful for the Committee to solicit comments on the guidelines from agencies and organizations which weren't present at the public meetings in order to get their input and support.

Dr. Osburn asked how ABRAC could reach these groups? Dr. Andow suggested forming a subcommittee to determine which audiences to target. Once the groups were identified, the subcommittee could act as liaison.

REPORT AND DISCUSSION OF NIH PUBLIC MEETINGS

Dr. Tolin reported that NIH had recently held eight public meetings during which four questions were posed about the future of the NIH Guidelines. She said they received many comments which hadn't yet been analyzed. Generally, there was strong support for retaining the NIH Guidelines. Only the University of California advocated a sunset clause. All others wanted the NIH Guidelines to continue in force. Industry stressed that the NIH Guidelines had become a national code of practice. She said that NIH has asked if the guidelines should continue to apply to recombinant DNA or be broadened to cover newer techniques. Responses to this question were split about 50:50, for and against.

Dr. Tolin noted that several people at the NIH meeting questioned why the USDA guidelines weren't published yet.

Dr. Tolin said the fourth question raised by NIH had to do with what role NIH should play in public education about gene therapy. Although NIH has approved four protocols for gene therapy, the IBC's expressed concern that they were not prepared to review these types of proposals.

Mr. Paul Stern said that he attended the NIH public meeting in Washington D.C., and that there had been overwhelming support

for continuing the NIH Guidelines. He noted that Dr. Henry Miller, FDA, had advocated a sunset clause.

Dr. Osburn clarified that the IBC at Davis wanted the NIH Guidelines to continue in force. However, some of the southern California campuses preferred a sunset clause.

Dr. Vidaver asked what comments had been made by IBC members at the NIH public meetings. Dr. Tolin replied that the IBC's expressed concern about their workloads. She reported that the IBC's expressed a need for guidance on the containment of plants and animals, the subjects of Appendices P and Q which are still under development. NIH is also working on guidelines for large-scale fermentation. NIH plans to publish all the new appendices to the NIH Guidelines in one package.

Ms. Cordle asked if there had been any discussion about the NIH Guidelines being nonrisk-based because they cover only recombinant DNA. Dr. Tolin replied this issue had not been brought up during the NIH public meetings.

Dr. Whitmore raised the issue of what the IBC's are actually doing in the absence of the NIH appendices on containment of plants and animals. He asked if they are working from earlier drafts of Appendices P and Q or waiting for publication. He also asked if the absence of the final appendices was influencing researchers who may be deciding not to undertake certain experiments. Dr. Payne replied that some IBC's had used the draft of Appendix P on containment of plants when designing P2 greenhouses for experimental work.

Dr. Vidaver asked about the timeframe for the Environmental Assessment (EA) supporting Appendices P and Q of the NIH Guidelines. Dr. Tolin replied that the EA should be completed by February 1991.

DISCUSSION OF THE PROPOSED USDA GUIDELINES AND THE ROLE OF ABRAC

Dr. Young asked the ABRAC members to consider how they wished the Committee to proceed. He said there are several areas where ABRAC could assist the Department, for example, in offering advice about potential exclusions from scope or discussion of how implementation of the USDA guidelines should be carried out.

Dr. Hill asked if nonmembers could work on ABRAC subgroups. Dr. Young said they could be brought in as resource people, but they could not be used to formulate policy.

Dr. Kemp suggested it would be worthwhile for the ABRAC to take up the issue of scope again, noting that much has occurred since the Committee's earlier deliberations on this topic. He noted that the OSTP scope differed from the scope proposed by ABRAC for the USDA guidelines. He said exclusion six of the OSTP scope had never been discussed by ABRAC.

Ms. Cordle agreed, clarifying that exclusion 5 in the ABRAC-developed USDA guidelines would include exclusion 6 in the OSTP scope. She said industry comments supported the ABRAC approach, and were generally against self-determination of whether or not an organisms is covered by oversight. She said there may be subsets of exclusion 5 which ABRAC could define further.

Dr. Bollinger inquired about the steps from here forward. He asked if the Competitiveness Council will review the comments on the OSTP scope principles. Ms. Cordle said she believed that OSTP will review the comments, respond to them, and publish a revised document. However, she noted that some observers believe enough time and energy has already been spent on scope discussions.

Dr. Tolin asked if the USDA guidelines would be held up until a final version of the OSTP scope has been published. Ms. Cordle replied that USDA had been told during earlier meetings that they would not have to wait.

Dr. Tolin expressed the view that ABRAC should reconsider its recommendations on scope. She noted that exclusions 4, 5, and 6 in the OSTP proposal are similar to type 2 modifications described in the USDA guidelines. Dr. Kemp agreed with this interpretation. He added that the OSTP scope excludes plants produced with tissue culture from oversight, yet these plants in greenhouses are covered by the NIH Guidelines.

Dr. Andow suggested that an ABRAC subcommittee could be formed to reexamine the scope issue.

Dr. Korwek said that he was not sure that continued discussion of scope would move the process ahead.

Dr. Whitmore stated that many questions remained unanswered in the absence of USDA guidelines. He said that had the USDA guidelines been published, NIH might have considered combining selected parts of the NIH and USDA guidelines, thus providing uniform guidance to researchers. However, there now seem to be many questions about how the whole system fits together. He expressed the view that addressing this issue is more important than continuing to work on scope.

Dr. Osburn asked Dr. Andow to present his ideas on the formation of new ABRAC working groups. Dr. Andow noted that the recent separation of the guidelines effort into principles and implementation may justify the formation of separate ABRAC working groups to address those areas. The principles working group would clarify the need for the guidelines and seek to involve additional scientific and professional associations in the guidelines effort. The implementation working group would solicit the input and support of IBC's in the implementation of the guidelines. He also suggested the formation of at

least one other working group to deal with issues to be identified by the Committee.

Dr. Whitmore cautioned against the formation of new working groups without careful consideration of new directions of the guidelines effort. He said the formation of working groups on principles and implementation might be interpreted as Committee endorsement of the separation of the two phases, an approach with which he did not agree. He urged the Committee to consider forming working groups that address the real problems the guidelines are facing even if those problems are non-scientific in nature.

Dr. Korwek expressed support for the formation of subcommittees, but he pointed out the importance of developing well thought-out goals and directions for them. He expressed uncertainty as to whether the concept of implementation of the guidelines involved IBCs, NEPA assessments, or other activities.

Dr. Young interpreted the Assistant Secretary's decision to divorce implementation from guideline principles as meaning that the guidelines will not be tied to funding or NEPA and that the Department will not tell IBCs how to operate. He said the Assistant Secretary was interested in a range of options for implementing the guidelines that he could discuss with General Counsel, the Office of Management and Budget, and various science and technology committees as needed. Even though there is a perceived need for guidance to IBCs concerning research field testing, Dr. Young acknowledged that the guidelines may never be published.

Dr. Kemp echoed the concern about decoupling principles from implementation of the guidelines. He recalled that the principles of the guidelines, as formulated by the Committee, implied a policy concerning their use by IBCs. Ms. Cordle pointed out that references to IBCs have been deleted from the guidelines.

Dr. Kline asked how the Federal Register announcement of the decoupling would read. Ms. Cordle read the current draft summary into the record. It said in part, "... these guidelines describe principles for assessing the confinement measures to promote safety. The guidelines are not mandatory. They are intended as points to consider to any principal investigators and institutions in determining conditions for safe research. The guidelines also encourage institutions to utilize Institutional Biosafety Committees to aid investigators in the safety evaluation of confinement design." Ms. Cordle emphasized that the guidelines were not for oversight and review of research, but to aid investigators in their safety evaluation and confinement design.

Dr. Kemp expressed hope that the scientific community would respond to the proposed guideline principles with its views of

a logical basis for implementation of the guidelines.

Ms. Cordle indicated that administrative and legal reviewers of the proposed guidelines would not agree to the use of the word "oversight" and also questioned the use of the term "safety evaluation."

Dr. Whitmore expressed concern about decoupling guideline principles from implementation and leaving compliance with the guidelines voluntary or discretionary. In his view, it reflected abandonment of the model of the NIH Guidelines and will leave an oversight vacuum that the regulatory agencies will feel obligated to fill.

Dr. Korwek expressed doubt that the Committee has much choice about accepting the decoupling of principles from implementation at this time. He expressed hope that publication of the guidelines as principles will stimulate a response from the scientific community that will lead to improved guidelines acceptable to all concerned.

Dr. Vidaver expressed the view that if the Committee finds the decoupling approach to be flawed, it should register its reservations. Dr. Sorensen agreed saying that implementation of the guidelines has been implicit in the Committee's discussions over the past few years and it is difficult to divorce these issues.

Dr. Osburn asked Dr. MacKenzie to summarize the results of a survey recently conducted by the National Biological Impact Assessment Program (NBIAP). Dr. MacKenzie reported that the purpose of the NBIAP survey was three-fold: to assess how the Coordinated Framework for Regulation of Biotechnology is providing biosafety assurances about field testing; to determine what impact, if any, the Coordinated Framework regulatory process was having on biotechnology communities and their ability to field test; and to gather suggestions for possible improvements in the Coordinated Framework.

Dr. MacKenzie identified the survey population as recipients of field test permits issued before January 1, 1990. The population consisted of 35 researchers representing 24 companies, universities and research organizations who had collectively received 65 Federal permits to conduct field tests with genetically modified organisms. The permits included 51 permits for plants and 14 permits for microorganisms.

Dr. MacKenzie reported that the researchers interviewed agreed by and large that the Coordinated Framework is working fairly well and that the APHIS staff has been helpful, courteous, and timely in the issuance of field test permits.

Dr. MacKenzie reported concerns from the survey about state regulation of biotechnology and duplicative permit applications

to EPA and APHIS. The survey population reported that pretest expectations concerning the biosafety of field tests were met by the tests conducted so far and that no surprises have occurred. The researchers surveyed indicated their intention to publish the scientific results of their field tests, but not the biomonitoring results in most cases.

Dr. MacKenzie indicated that there was common agreement among the researchers surveyed that a common pool of biological monitoring information based on field test experience would be of assistance to researchers planning field tests and would form the scientific basis for eventual deregulation. There was a high frequency of willingness expressed to contribute to the information pool and a belief that industry should be included since industry has done most of the field testing.

Dr. Osburn commented on the difficulty of funding agricultural field tests, particularly in the animal health area, for both industry and universities.

Dr. MacKenzie described plans for a future survey of researchers who have reported difficulty in working within the Coordinated Framework. He said the results of such a survey could be helpful in promoting better compliance with the Coordinated Framework and avoiding both unintentional discouragement of field testing and defiant field testing without the necessary permits.

Dr. Kemp observed that NBIAP will probably have to take the initiative in collecting negative results of biomonitoring. Dr. MacKenzie agreed and described ongoing discussions in that area. One industry representative, for example, reported that his company hired five technicians to do hundreds of microbial plate counts on samples from various locations and distances around a Rhizobium field test site. From these tests, the maximum distance that the engineered microbe migrated in the soil appeared to be seven inches.

Dr. Tolin observed that maximum migration distances of microbes in soil from actual field tests would have a very direct bearing on how confinement practices and research guidelines are drafted.

Dr. Osburn thanked Dr. MacKenzie for his presentation on the NBIAP survey.

SUMMARY OF APHIS ACTIVITIES

Dr. Osburn asked Dr. John Payne of APHIS to summarize recent APHIS activities. Dr. Payne said he would describe activities that may point in the direction of deregulation as well as current activities.

Dr. Payne recalled that APHIS proposed its revised plant pest regulations in 1986 and finalized them in 1987. Since then a number of field tests have been conducted and a considerable amount of biosafety and biomonitoring data has been collected. There is thus a growing body of data that can be used as a basis for deregulation.

Dr. Payne described a deregulation process based on petitioning. He said an individual can petition the agency to deregulate an organism. The general form a petition should take is described in the regulation [7 CFR 340.4], but it does not provide details. A petition must give data and analysis to support why an organism no longer needs to be covered by regulation. He said APHIS is in the process of discussing what data will be needed, and it will provide guidance soon.

Dr. Payne noted that APHIS expects to receive petitions within the month for deregulation of organisms which have been field tested during the past three to four years. Once a petition is received, APHIS will do a cursory review to determine if the petition contains adequate data including any adverse data. The agency will then publish a notice in the Federal Register and it may also hold a public meeting.

Dr. Payne reported that APHIS is currently conducting a series of meetings on large-scale testing of groups of crop plants. These include meetings on oilseed crucifers at Cornell University in October, 1990; corn/maize and wheat at Keystone, Colorado in December, 1990; rice in Asia at some future date; and cotton and two other crops to be selected in 1991. Information gathered at these meetings will be used to support decisions on large-scale testing and it may also be useful in relaxing regulatory review of small-scale field tests.

Dr. Payne said that APHIS is interested in explaining to the research community how to apply for a permit. It plans to publish a handbook with sample applications which should be especially helpful to the academic community. According to Dr. Payne, APHIS is also looking at a more flexible regulatory approach which might involve a notification scheme for small-scale tests where APHIS has already completed EA's on similar tests.

Dr. Korwek asked why APHIS could not deregulate on its own initiative.

Dr. Payne responded that the time required to develop an internal consensus makes it difficult for the agency to deregulate on its own. He interpreted the current absence of petitions to deregulate as a sign that there is not a strong enough need for or commitment to deregulation at this time.

Dr. Korwek observed that petitions from companies to deregulate may be so narrow in scope that they will not result in exemptions for the industry.

Dr. Kemp asked how anyone else could ever make use of an exemption if it is for a proprietary product. Dr. Payne, using the transgenic tomato as an example, said that the first petitions may, in fact, be very narrow. However, as subsequent petitions are received they will build upon one another, eventually widening to a broader exemption. He added that there is a need to build public confidence gradually.

Dr. Tolin asked about NEPA and its implications for deregulation. Dr. Payne replied that APHIS staff members are currently discussing whether an exemption requires an EA or some other type of documentation.

Dr. Korwek asked if prior exemptions required EA's. Dr. Payne said the exemption for interstate commerce did not require an EA.

Dr. Tolin asked if ABRAC might play a role in the deregulation process. Dr. Payne replied that it is unclear how that would work. He added that the stringency of confinement procedures in applications for small-scale field tests appears to be decreasing because early applicants went beyond what was necessary.

Dr. Andow asked how exemptions resulting from industry petitions for specific proprietary constructs could be used by university researchers. Dr. Payne replied that petitions to deregulate would not be based on confidential business information. He said the data must be available for public debate.

Mr. Stern asked how much time is covered by an APHIS permit. Dr. Payne responded that permits normally cover one year, but they can be reissued. Some crops, like walnuts, require a permit which covers a longer period.

Dr. Kemp asked if once a company receives an exemption for a particular construct, if other petitioners could use the data in the petition to make a subsequent petition to exempt a slightly different organism. Dr. Payne replied that additional data would be required about the specific construct, but data from earlier petitions may be used if relevant. He added that academic researchers may petition to exempt broader classes of organisms.

Dr. Andow noted that the petition process will lead to the proliferation of gray literature that is not subject to peer review. He asked how this literature would be evaluated. Dr. Payne said the general standard for evaluation is scientific peer review. He said APHIS tries to approximate the level of scientific peer review in its review process by using its own

scientific staff as well as public hearings when needed. He said APHIS may also ask ABRAC to review certain applications.

Dr. Vidaver stated that the reason that there may be no petitions yet is that it is difficult to obtain the data to support petitions without extensive experimentation. Thus, there is a "catch 22" situation. She said she had encountered this when trying to deregulate a non-modified organism.

Dr. Payne responded that APHIS has received no formal petitions to deregulate. He explained that the case Dr. Vidaver referred to involved a taxonomic question and that this could be dealt with during a comment period rather than a formal petition.

Dr. MacKenzie asked how the recent deregulation of the interstate shipment of genetically engineered Arabidopsis was initiated. Dr. Payne replied that the Arabidopsis exemption was initiated within APHIS following discussions with researchers who suggested that research was being unnecessarily slowed down by the need for movement permits.

Dr. MacKenzie asked if other organisms such as carrots could be exempted from the need for a permit for interstate movement. He noted that many agricultural researchers were put off by the exemption for movement of Arabidopsis when there are no such exemptions for common food crops.

Dr. Payne responded that other organisms could be exempted. He noted that the move to exempt Arabidopsis from the need for permits for interstate movement was self-initiated by APHIS as a result of discussions with researchers. He said a similar approach to Rhizobium is stalled because of uncertainties about microbial competition. He noted that the Rhizobia are still on the list of regulated items, except for some specific strains which are not regulated.

Dr. Payne added that the Triplett proposal at the University of Wisconsin indicated that researchers still want some sort of environmental assessment to be performed before going to the field with Rhizobia. He wondered if delisting Rhizobia and other low risk organisms would really confer the advantages that researchers expected. He suggested that some kind of notification procedure might be a useful alternative to outright delisting.

Dr. MacKenzie reported that respondents to his survey stated that this is not the time for deregulation because of public opinion.

Dr. Young asked if APHIS had used the guidelines in any way in its review process. Dr. Payne replied that the guidelines generally did not offer enough specifics to be useful for deciding whether to issue permits. He acknowledged, however, that there is a real need for guidance for the IBC's.

Dr. Young stated that it would be useful to issue a single handbook which would incorporate both the principles of the guidelines and advice from APHIS about the permitting process.

Dr. Payne replied that the APHIS handbook would contain very specific guidance on how to obtain a permit and the guidelines may not fit this purpose. He said the general view of APHIS is that there is no need to set up a quasi-regulatory process involving the IBC's. He added that if there is an identifiable risk involved, there is most likely a regulation to cover it. However, he added, IBC's should be given oversight and guidance so that they can assist researchers. He said most IBC's have not thought through the ecosystem effect issues involved with field testing.

Ms. Cordle asked if the advice given to IBC's in the guidelines will conflict with the advice offered by APHIS. Dr. Payne said the APHIS publication would go over the form for a permit application, question by question. He said he would expect the two sources of advice to be consistent.

Dr. Tolin asked if the advice given would differ about which organisms involve risk. Dr. Payne said there is a gray area of disagreement over which organisms ought to be covered, but ABRAC and APHIS need not work at cross purposes. He said it is surprisingly difficult to deregulate the Rhizobia, for example, because negative data documenting safety is not always recorded or published.

Dr. Osburn thanked Dr. Payne for his presentation.

ABRAC CHARTER AND PROCEDURES

Dr. Young distributed the ABRAC charter and operating procedures. He apologized to the new members for not doing so sooner. He said one area which has been left unresolved is conflict of interest. He said this would need to be addressed in detail at a later date.

November 27, 1990

NASULGC REQUEST FOR ABRAC TO CONSIDER DEREGULATION

Dr. Osburn referred the Committee to Document 139 (Appendix C) which is a letter from the National Association of State Universities and Land Grant Colleges (NASULGC), Committee on Biotechnology, requesting that ABRAC take on the issue of deregulation. Dr. Osburn asked the Committee for their comments on this request.

Dr. Young reported that he had met with APHIS and OGC to discuss the legally appropriate ABRAC role in the deregulation process. He said he had been advised that ABRAC can participate in

information gathering and review to support the petitioning process for deregulation.

Dr. Korwek expressed doubt that ABRAC could be a petitioner because the Committee is advisory.

Dr. Payne said that any entity can petition APHIS, and the ABRAC would have standing under the APHIS rules. He said he could envisage several roles for ABRAC in the petitioning process. ABRAC could collect data and be the petitioner, or could facilitate petitions by another party, or could examine data in petitions and provide scientific review.

Dr. Korwek questioned if ABRAC should be the petitioner. He asked Dr. Young if this had been discussed with OGC, noting that there is a fine line between review and advocacy.

Dr. Young replied he had not specially asked OGC if ABRAC could legally be a petitioner. His discussions had focused on ways ABRAC could assist APHIS.

Dr. Osburn asked OAB to obtain clarification on this point from OGC and to define the range of actions ABRAC could take. Dr. Young agreed to do so.

Dr. Tolin suggested that at the next meeting the Committee should study the APHIS rules concerning petitioning for deregulation.

Dr. Andow expressed uncertainty that ABRAC should get involved in the petitioning process since the Committee is advisory.

Ms. Cordle said that if APHIS decided to deregulate on its own, ABRAC might be able to advise APHIS on scientific issues related to deregulation.

Dr. Payne said APHIS welcomed good advice from any source. However, he questioned whether such a role was consistent with the ABRAC charter.

Dr. Korwek asked if NASULGC expected ABRAC to be the prime mover for deregulation. He said he was opposed to ABRAC taking on this role.

Dr. MacKenzie commented that there is no group which is willing to be the prime mover for broad deregulation. The companies will petition for narrow exemptions. The university community does not have the resources to pursue deregulation. NBIAP does not have the resources to be the petitioner. He said there is a need to build a partnership; it may be premature, but ABRAC should take a look at the issue.

Dr. Gerber asked if a petitioner has to have evidence gathered through his/her own actions or access to unique data.

Dr. Payne replied that this is not the case. Data may be obtained from public sources to support petitions. He added that during the comment period on a petition for deregulation, the petition could be broadened by comments.

Dr. MacKenzie and Dr. Tolin stated that the question before ABRAC is who is going to step forward and take on this task. Dr. Tolin said the Committee should consider this at the next meeting, after the options had been clearly outlined.

Dr. Vidaver suggested that ABRAC would need more funding to take on this role.

Dr. MacKenzie said NBIAP could play a role in helping to put together the data to support petitions. He said he would work with OAB staff to develop options for consideration by the Committee.

Dr. Payne informed the Committee that he would provide a list of all the permits issued by APHIS.

COOPERATIVE ACTIVITIES BETWEEN ABRAC AND NBIAP

Dr. Young presented selected background information on the National Biological Impact Assessment Program (NBIAP) for the Committee. He referred to the initial recommendation to USDA by the National Association of State Universities and Land Grant Colleges (NASULGC) to establish NBIAP. He also referred to the section of the ABRAC Charter that specifically mentions interaction between ABRAC and NBIAP. He then introduced Dr. David MacKenzie and asked him to update the Committee on recent NBIAP activities.

Dr. MacKenzie indicated that after several years of relatively low funding, the NBIAP program received a three-fold increase in its budget for the coming fiscal year. He said NBIAP disperses most of its funds through Virginia Polytechnic Institute and State University (VPI) which subcontracts to other institutions.

Dr. MacKenzie reported that NBIAP operates an electronic bulletin board with 1200 subscribers, most of whom are scientists. The electronic bulletin board serves as a gateway to several databases including two new ones on state contacts and a worldwide directory of scientists working on the application of biotechnology to plants, animals and mircroorganims. He also reported that NBIAP is currently updating a database of IBC's.

Dr. MacKenzie said that NBIAP is currently upgrading its software to assist scientists in generating applications for permits to field test. He said Ms. Suzanne Henry of his staff would be available at the break and at lunch to demonstrate this program to anyone interested. He also described plans for NBIAP

staff or contractors to visit campuses and assist scientists in developing applications for permits to field test. The opportunity for such visits will be announced to Directors of State Agricultural Experiment Stations.

Dr. MacKenzie reported that, as Director of NBIAP, he is involved in a number of additional activities. These include working on the CSRS NEPA regulations, advising the agency on biotechnology construction grants, conducting program reviews, and undertaking international activities with the Organization for Economic Cooperation and Development, the US-EC Task Force on Biotechnology Research, and the Swedish Academy of Science. He is also in charge of publishing the proceedings from the Kiawah Island Symposium on the results of field testing.

Dr. MacKenzie reported that NBIAP will be forming an interagency working group to capture biological monitoring data which are key to making safety decisions. Without such a working group, he said, agencies may be duplicating efforts.

Dr. MacKenzie noted that the 1990 Farm Bill calls on the Department to devote one percent of the funds it spends for biotechnology research to risk assessment research. He said the USDA is still working on the details of implementing this legislation, and that NBIAP would probably play a role in deciding what research areas should be pursued. He added that, in his opinion, there is a need to target this new program to fill knowledge gaps and to direct resources to problem areas.

Dr. MacKenzie mentioned several possible areas where ABRAC could help NBIAP. These included: help in designing the biological monitoring base; help in planning the risk assessment program called for in the Farm Bill; help in providing details to the confinement matrix of the NBIAP system which would be consistent with the guidelines; help in conducting the program review of the NBIAP program; and help in future years in dealing with the issue of deregulation.

Dr. MacKenzie indicated that NBIAP could support ABRAC in a number of different ways including providing data to support petitions to deregulate, providing data on target projects being considered by ABRAC, assistance in NEPA compliance, such as the EA on the Triplett experiment, and providing results of surveys of the agricultural research community. He added that there is a need for continuing open communication between NBIAP and ABRAC. He requested views of ABRAC members on their expectations of the NBIAP program.

Dr. MacKenzie concluded by offering advice to the Committee. He suggested that the ABRAC move forward and solicit applications for review whether or not the guidelines are formalized. He recommended that ABRAC support the publication of the guidelines as principles as soon as possible, and let the USDA agencies work on the contentious aspects of implementation. Finally, he

urged ABRAC to take an active role in the process of petitioning for deregulation of biotechnology. He said if ABRAC did not take on this role, he would consider moving the NBIAP program into that role.

Dr. Bollinger asked what percentage of the NBIAP users are public versus private researchers and what attempt NBIAP had made to increase the number of users. Dr. MacKenzie replied that NBIAP is studying the users' profiles. Although he had no hard data yet, he surmised that most NBIAP users are in the public sector. He cautioned that significant expansion of the number of NBIAP users would bring pressure to charge for its services. Currently, he said, the 800 number allows for 250,000 users and a $30,000 annual phone bill. The current budget covers this cost, but a significant expansion might make it impossible to continue to provide information for free.

Dr. Kline asked Dr. MacKenzie's view on the sufficiency of data at this time to support petitions for exemption of broader classes of organisms and who should prepare these petitions. Dr. MacKenzie replied that the data may not yet be sufficient to make a convincing case for deregulation and that he was not sure who should actually prepare petitions to that effect.

Dr. Hill asked Dr. MacKenzie to clarify his responsibility for review of grant applications submitted to CSRS. Dr. MacKenzie replied that most of the grant applications he reviews are requests for funding the construction of biotechnology facilities rather than competitive research grants. The funds for these construction grants are appropriated by Congress for specific facilities.

Dr. Young asked Dr. MacKenzie how ABRAC might review requests for field tests and how this would fit in with the reviews conducted by APHIS. Dr. MacKenzie replied that ABRAC could provide review for cases such as the Rhizobium experiment proposed by Dr. Triplett of the University of Wisconsin which didn't seem to fit anywhere in the regulatory framework.

Ms. Cordle noted that the Triplett experiment was low-risk and should not have had to come to a national scientific advisory group such as ABRAC. Dr. Payne agreed, stating that if ABRAC begins to review low-risk experiments routinely, there will be negative consequences for researchers because every experiment will then require a national level review. He added that there is a need to empower the IBC's to give advice to researchers and let similar experiments go forward.

Dr. MacKenzie expressed concern about the slow pace of providing help to the scientific community on the conduct of field tests. He referred to a discussion on interim guidance in the minutes of a previous ABRAC meeting. Dr. Young replied that the slow pace of providing guidance to the scientific community is not due to a lack of effort on the part of the ABRAC. He credited

the ABRAC with providing sound scientific advice on the guidelines to the Secretary as authorized by the ABRAC Charter. He reminded those present that the ABRAC is limited in what it can do once it has developed and forwarded its advice on a given issue.

Dr. MacKenzie encouraged the gathering of data now to support deregulation so in that 1994 or 1995 the data will be organized and accessible to support petitions. Dr. Gerber stated that CSRS should have a role. He asked if the Current Research Information System (CRIS) could be modified to collect pertinent data. He noted that ABRAC might study this issue and make recommendations about the CRIS system.

Dr. Tolin supported Dr. MacKenzie's view that ABRAC needed to review applications in order to fine tune the guidelines. She said there is a particular need to develop the details of confinement levels for specific organisms.

SUPPORT FOR THE GUIDELINES

Dr. Osburn asked the Committee to consider what actions it could take to help move the guidelines forward.

Dr. Kemp stressed the importance of the ABRAC demonstrating its support for Dr. Hess's efforts to get the guidelines published. He proposed that the Committee pass a resolution expressing support. After some discussion, Dr. Osburn asked Dr. Kemp, Dr. Tolin, and Dr. Vidaver to draft such a resolution during the lunch break.

AUBURN TRANSGENIC FISH EXPERIMENT

Ms. Cordle updated the Committee on the transgenic fish experiment at Auburn University. She reported that the Administrator of CSRS signed the EA/FONSI on November 15, 1990 and that the notice of availability of the EA was published in the Federal Register on November 21, 1990.

Ms. Cordle summarized the additional safety features designed to confine the experimental fish to the Auburn research ponds that were developed since the proposed EA was published in February, 1990. These included newly constructed ponds located at a higher elevation than the old ponds and the use of catch-basin ponds, French drains, layers of gravel, and natural fish predators.

Ms. Cordle outlined some of the special problems and lessons learned from the review of the Auburn proposal. Special problems included the extrapolation from performance in a research environment to performance in a natural environment, and the prediction of survival and selection pressures. One of

the lessons learned from the Auburn exercise was that the design of a research facility is more important than whether it is indoors or outdoors and that well-designed outdoor ponds may actually be better contained than many indoor fish hatcheries

Dr. Bollinger asked Ms. Cordle to comment on the costs and the benefits of the Auburn experiment.

Ms. Cordle addressed the benefits first. She said that the purpose of the Auburn experiment was not to develop an improved species of carp, but to learn how best to do transgenic fish research. She said the Auburn experiment is using carp as a model for catfish. There is no intent of commercializing results from the current basic research. However, in the long-run, applying biotechnology to improving aquaculture is important because there is an unmet demand for more fish worldwide and the world fish catch is declining.

Ms. Cordle estimated that it cost more than $100,000 to prepare the environmental documentation for the Auburn experiment largely because it was a precedent setting case. She observed that some people believe there is a loophole in the regulations for transgenic fish. Also, the EA was difficult to prepare because of complex ecological questions.

Dr. Young estimated that the total cost for Auburn and the government was in the neighborhood of $200,000-250,000. He explained that Auburn had improved its research facility by building new ponds, rebuilding old ponds, and constructing a new fish hatchery.

Dr. Kemp noted that the carp were mircroinjected with recombinant DNA with a viral promoter. He asked why the fish were not a regulated item. Ms. Cordle replied that there was no commercial intent so the experiment did not fall under TSCA. She said APHIS had determined that it did not have jurisdiction. Dr. Payne added that had the fish been transformed with a modified retrovirus, APHIS might have had jurisdiction because it could have been considered an experimental biologic. However, since the fish were modified by direct injection, this was not the case.

Dr. Kemp asked if microprojectiles or ballistic methods of transformation would be regulated. Dr. Payne replied that regulation of those methods is not contemplated if a vectoring agent or experimental biologic is not involved.

Dr. Korwek noted that injection of a biologic would be regulated as a biologic. Dr. Payne replied that the determining factor is not injection or ballistic projectiles, but whether the experimenter starts with a biologic that determines if it is a regulated article. Ms. Cordle noted that this interpretation differs from that generally read into the Plant Pest Act.

Dr. Korwek wondered that if injected or ballistic DNA is not a biologic, then perhaps it would be considered an animal drug. He asked Ms. Cordle if OAB had received an opinion from the FDA Center for Veterinary Medicine (CVM). Ms. Cordle replied that representatives of several agencies including FDA attended an interagency meeting on the Auburn proposal and that the FDA representative had deferred on treating DNA in the Auburn experiment as a drug.

Dr. Korwek observed that the human counterpart is regulated as a drug. Dr. Tolin gave, as an example, human gene therapy using the Rous sarcoma virus (RSV) promoter. Ms. Cordle reiterated that FDA chose not to treat the Auburn experiment as one involving an experimental drug. Dr. Korwek asked if this was a policy decision on the part of FDA or an ad hoc determination. Ms. Cordle replied it was ad hoc.

Dr. Whitmore expressed satisfaction that the EA had been published. He recalled that he had voted against the experiment going forward at an earlier ABRAC meeting. He mentioned the time pressure on the Committee at that time because Auburn was concerned about keeping the adult fish alive and in good condition indoors. Ms. Cordle responded that Auburn had received permission, under the NIH Guidelines, to move the adult brood fish outdoors. Since that time the remaining fish had done well and were ready for spawning.

Dr. Kline asked if the Auburn experiment was necessary for the whole area of transgenic fish experimentation to move forward. Ms. Cordle replied that it is difficult to know, but more data are needed to address many scientific questions about transgenic fish. She added that Auburn wanted to do the experiment because the information it will provide is essential in moving toward the goal of applying biotechnology to commercial aquaculture.

Dr. Kemp said he was still unclear about which items are not regulated. He asked if there are any types of transgenic plants which are not regulated. Ms. Cordle said that, currently, certain plants are not regulated because they are transformed without vectors which are considered to be plant pests. But this may change if APHIS implements the OSTP scope definition. She noted that the regulatory system in evolving.

Dr. Kemp asked about a hypothetical situation in which he synthesized a promoter which is entirely novel and used either microinjection or ballistics to introduce the DNA into the plant. He wanted to know if this would be regulated. Dr. Payne said that it would be regulated because the promoter is unknown and there would be uncertainty as to its effects on the organism and the environment. Dr. Payne stated that an unclassified promoter is a regulated article. Dr. Kemp and Dr. Tolin questioned the basis of this statement.

Dr. Payne acknowledged that it is difficult to be sure because this is a hypothetical example. He noted that in the real world there are plants which are not regulated. He said APHIS believes this is appropriate until there is a demonstrable risk. Dr. Payne added that some have argued that APHIS needs additional regulatory authority to cover direct injection and ballistic insertion of DNA. He countered that until there is a demonstrable risk, there is no need for additional authority and that the Plant Pest Act is sufficient.

As an example, Dr. Payne mentioned that a corn gene and a petunia promoter could be inserted ballistically into a petunia plant and grown in a field without a permit. He expressed the view that IBC's should advise researchers on how to proceed with those experiments safely. On the other hand, use of a vectoring agent such as a Ti plasmid or a gemini virus would require APHIS review and issuance of a permit.

Dr. Andow commented that OAB had accomplished a great deal in preparing the EA. He expressed overall agreement with the Finding of No Significant Impact (FONSI). In his view, Auburn now has the very latest technology and excellent fisheries research facilities and these along with the new confinement procedures led to a FONSI.

However, for the record, Dr. Andow expressed the view that some of the arguments in the EA are weak or inappropriate and could be strengthened. For example, he felt that the lower performance of mirrored carp compared to common carp in the environments surrounding the Auburn research facility should have received greater emphasis. He also expressed the view that the small size of the population is important not because it makes it difficult for the population to become established, but because the mitigation measures in the event of escape would be easier to implement.

Ms. Cordle questioned the ease of mitigation when it involves a 50-mile stretch of the Saugahatchee Creek between the Auburn research facility and the Yates Reservoir.

Dr. Andow contended that the domestication argument in the EA is weak and unsubstantiated by the literature. He further contended that the stability of the environment doesn't make as much difference to the colonization of a new ecosystem as the invasiveness of a particular genotype.

Ms. Cordle explained that the EA does not rest on any one of these arguments, but rather on the collective consideration of a complex set of factors. Dr. Andow replied that research is needed to see if the factors are statistically independent.

OAB UPDATES

Dr. Young reported that the Rhizobium experiment described by Dr. Triplett at the last ABRAC meeting had gone forward into the field without further delay and was proceeding smoothly.

Dr. Phillips reported that the approval to field test a live recombinant Brucella vaccine has been given by APHIS. However, he said Dr. Roger Smith at Texas A&M reported that the experiment has not begun yet.

Dr. Young reported that FSIS has completed work on its proposal on slaughter of "non-transgenic animals". The agency is now working on its proposal for slaughter of transgenic animals. ABRAC may be requested to comment on this proposal when it is completed.

Dr. Young reported that the USDA Biotechnology Council has been meeting regularly to discuss items of cross-cutting interest. He said the council consists of USDA agency middle managers who have day-to-day responsibility for biotechnology.

Ms. Marti Asner reported that OAB had recently completed work on a fact book which describes each of the 14 USDA agencies involved in biotechnology. The book covers all USDA programs and activities in biotechnology. She said the book is expected to go to press in December 1990.

Dr. Bollinger asked if the fact book will cover every research project funded by USDA. Ms. Asner replied that the book will provide a general overview of programs rather than specific projects. It will provide phone numbers for contact persons who can provide more information on specific projects.

Dr. Young noted that the handbook entitled Agricultural Biotechnology: An Introduction to Field Testing, is very popular. He said OAB is currently negotiating to buy more copies from Mississippi State University.

ABRAC PROCEDURES FOR CONFLICT OF INTEREST

Dr. Young referred the Committee to the one page statement on conflict of interest prepared by Mr. Robinson (Document 137 which is attached as Appendix D). He reported that Mr. Robinson had attended a meeting on conflict of interest sponsored by NIH and had drafted this statement as a starting point for ABRAC thinking on the issue. He said that eventually the Committee must come to closure and adopt a conflict of interest policy.

Dr. Korwek said the document is a good beginning, but in his view, it needed a legal orientation. He asked if Mr. Stern could review and refine the document for consideration at the next meeting. Dr. Osburn requested that Mr. Stern do so.

Dr. Young asked the Committee to review the ABRAC procedures outlined in Document 15A. These procedures were drawn up during the early days of the Committee. Some members had asked questions about these procedures.

Dr. Osburn asked the Committee to review both Document 15A and Document 137 and submit comments to OAB prior to the next meeting.

RESOLUTION SUPPORTING THE GUIDELINES

Dr. Kemp read the resolution which the ABRAC drafting group had developed (included as Appendix E). Dr. Kemp asked the Committee to consider if they wanted to add a supplemental statement on implementation to the resolution. He moved that the Committee approve the resolution. The motion was seconded.

Dr. Tolin offered an amendment that an additional statement be appended to the resolution which would urge implementation of the guidelines.

Dr. Osburn called for discussion on the amendment. Dr. Hill said he would prefer not to have a statement on implementation because it might undermine the ability of the Department to get the guidelines published immediately. Implementation could be dealt with later. Dr. Tolin said that she also was not sure if implementation should be discussed in the resolution. She said that implementation could be mentioned in a letter to Dr. Hess which would accompany the resolution.

Dr. Kemp called for the question on the amendment. It was defeated, four in favor and eight opposed.

Dr. Osburn called for discussion of the resolution. There was none. The resolution was passed unanimously.

Dr. Vidaver asked if implementation should be discussed in a letter from the ABRAC to Dr. Hess. Dr. Osburn said a letter should encourage Dr. Hess to do whatever is appropriate at the time to get the guidelines published and implemented. Dr. Andow said this could also be done verbally. It was agreed that the drafting group would draw up a letter.

DISCUSSION OF NEW ABRAC WORKING GROUPS

Dr. Osburn asked for discussion on the proposal to form ABRAC working groups on significant issues. He said Dr. Andow had suggested some possible topics for working groups during the last ABRAC meeting, and several topics had been identified during the current meeting. Some working groups could be formed immediately, while others were dependent on the publication of the guidelines.

Dr. Osburn mentioned suggested topics for working groups including risk assessment research and priority setting, databases and review of the NBIAP system, principles and constituency development for the guidelines, and implementation of the guidelines.

Dr. Osburn asked if there were other suggestions. Dr. Young said a working group could deal with the petitioning process for deregulation. Dr. Tolin agreed. Dr. Young said Mr. Stern was available to work with this group. Dr. Korwek asked what the terms of reference for such a working group would be. Dr. Young replied that the group would define alternatives and/or options for ABRAC. These options could then be discussed with OGC. This would allow the full ABRAC to take a more comprehensive approach to the issue of deregulation.

Ms. Cordle suggested a working group could examine why the academic community is not fully involved in field testing. This would include the issue of compliance with regulatory requirements as well as an examination of broader factors.

Dr. Tolin suggested a working group could consider organism-specific confinement issues under the guidelines. Dr. Young agreed this would be useful, noting that APHIS is also gathering information about confinement. Dr. Tolin stated that this needs to be done before risk assessment studies are undertaken. Dr. Kemp said these data need to be validated through peer review to determine if they are accurate. Ms. Cordle asked if the working group on confinement would also deal with classification or organisms under the Guidelines. Dr. Tolin said that confinement and classification of organisms fit together and could be handled by one working group.

Dr. Vidaver said the EPA has an advisory committee that is looking at similar issues. She suggested an ABRAC working group could contact this group and work on interagency harmonization of biotechnology issues.

Dr. MacKenzie asked if meetings of these proposed working groups had to be announced in the Federal Register. Dr. Young replied that they had to be announced and open to the public. This would assist in building public confidence and strengthen the support for the guidelines.

Dr. Tolin suggested that at the next meeting ABRAC consider a terms of reference for each group, and then decide which groups to pursue. Dr. Osburn agreed. He asked for volunteers to develop a one page terms of reference for each of the proposed working groups. The volunteers with the chairs listed first were as follows:

Risk Assessment/Priority Setting	Tolin, Bulla
Data Collection/Database Systems	Andow, Osburn

Regulatory Relaxation/Harmonization	Vidaver, Korwek, Kemp, Bollinger
Academic Field Testing	Hill, Kline
Organism Classification/Confinement	Kemp, Witt, Tolin
Constituency Development	Sorensen, Andow
Implementation Options	Whitmore, Bulla, Hafs
Food Safety	Witt, Tolin, Osburn

Dr. Korwek asked if ABRAC could afford to operate so many working groups. Dr. Young replied that no more than three could be funded, but he urged the Committee to develop terms of reference for all the proposed groups and then decide at the next meeting which groups to pursue.

Dr. Osburn charged the chair of each group to work with the other volunteers to draw up a one page terms of reference for each working group. They should be sent to OAB by January 11, 1991 in order to be be circulated to the entire committee for review before the next ABRAC meeting.

UPDATE ON THE GUIDELINES

Ms. Cordle reported that she had been in contact with Dr. Hess's office, and that there had been some movement in the discussions with OMB and CEQ about the guidelines. She said that they may be published as principles during the next few weeks. Dr. Osburn said he was pleased to hear this, but given earlier assurances, he would only be optimistic when he saw the guidelines in the Federal Register.

DATE OF THE NEXT ABRAC MEETING

After some discussion of members schedules, it was decided that the next ABRAC meeting would be held February 20-21, 1991 in Washington, DC.

SUPPORT OF ABRAC FOR THE GUIDELINES

Dr. Osburn asked that the text of the resolution supporting Dr. Hess in his efforts to get the guidelines published and the text of the accompanying letter be entered into the minutes. These are attached as appendix E. The resolution passed unanimously and all the members present signed the letter and the resolution.

Dr. Osburn said that he would present the letter and resolution to Dr. Hess personally the next day at the Kiawah Island symposium. An additional copy would be mailed to his office.

He asked Dr. Hill and Dr. Korwek if they would join him for the meeting the next day with Dr. Hess to present the resolution on behalf of the Committee. They agreed to do so.

RECOGNITION OF THE SERVICE OF MS. ELSIE BROWN

Dr. Osburn reported that because Ms. Elsie Brown is retiring, this would be her last meeting with the ABRAC. He said she had been a great help to the Committee and that her efforts were sincerely appreciated.

Dr. Kemp proposed that the entire Committee go on record as recognizing Ms. Brown and her excellent support for the ABRAC. The Committee agreed to do so. Dr. Kemp added that they wished her success in her retirement.

Dr. Osburn asked if there were other items of business. There being none, he adjourned the meeting.

Martha Steinbock
Rapporteur

Alvin Young
Executive Secretary

Daniel Jones
Rapporteur/Editor

Bennie Osburn
Chair

LIST OF APPENDICES

APPENDIX A

VISITORS PRESENT AT ABRAC MEETING OF NOVEMBER 26-27, 1990

Martin Terry, Animal Health Institute

Horst Fischer, Environmental Agency, Germany

Scott Shore, North Carolina Department of Agriculture

Steve Clapp, Food Chemical News

Rudolph Casper, BBA, Germany

Kornelia Smalla, Hygiene Institut, Magdeburg, Germany

Suzanne Henry, USDA Cooperative State Research Service

Celine Handfield, Environment Canada

United States Department of Agriculture

Office of Agricultural Biotechnology

Administration Building
Room 321-A
Washington, D.C.
20250-2200
(202)447-9165

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November 1, 1990

Dear Participants and Interested Parties:

On behalf of the USDA, I want to thank you for your participation and interest in the public meetings on the draft guidelines for "Research Involving the Planned Introductions Into the Environment of Organisms with Deliberately Modified Hereditary Traits" (***Guidelines***) held in September, 1990. Your thoughts and ideas have supplied the Department with useful information. I am pleased to enclose a copy of the summary of comments obtained from the meetings.

USDA will be publishing the ***Guidelines*** in the ***Federal Register*** soon. If you have additional comments upon publication which you feel would assist the Department in finalizing the guidelines, please direct them to the designated official.

Thank you again for your participation and interest in assisting the USDA in this important effort.

Sincerely,

Alvin L. Young

ALVIN L. YOUNG
Director
Office of Agricultural Biotechnology

Enclosure

Comments from the Five Public Meetings
Held on the Guidelines
September, 17, 19, 21, and 26, 1990

The following the comments are from the five public meetings held on the draft guidelines entitled "Research Involving the Planned Introduction Into the Environment of Organisms with Deliberately Modified Hereditary Traits" (guidelines) held in Sacramento, CA on September 17, 1990, in St. Louis, MO (2 meetings, a.m. and p.m.) on September 19, 1990, in Raleigh, NC on September 21, 1990 and in Washington, DC on September 26, 1990. There were 85 participants who registered for the meetings. Staff members of the OAB in attendence were: OAB Director, Dr. Alvin Young; Dr. Marshall Phillips; Mr. Milton Robinson; Dr. John Gerber; Mr. Paul Stern, Esq.; Ms. Maryln Cordle; and Ms. Marti. Two members of the Agricultural Biotechnology Research Advisory Committee (ABRAC) attended each meeting and participated in the discussions.

Mr. William Woods, Office Support Services, Washington, DC, attended and recorded a transcript of the meetings.

The meetings were held in an informal setting. Dr. Young, made a brief presentation of the USDA's interest in biotechnology and introduced the guidelines. Members of the audience had received copies of the guidelines either in advance or at the meeting. Mr. Milton Robinson served as facilitator of the meetings. He invited everyone to participate in both a formal and informal manner. He introduced the staff and requested that when they spoke as professionals and not as staff to so indicate. He invited the ABRAC members to participate in the same manner. The comments from the audience were written in brief form on flip charts so that the participants could judge the how accurately their comments were recorded. Drs. Phillips and Gerber made notes of the points and collected comments during the discussions and conversations. The staff made an effort to capture all distinct opinions, questions and ideas expressed to staff members at the meetings which are included in the compilation. These comments have been reconciled with the flip charts and the notes taken, but not with the transcript.

There was extensive participation in the meetings by members of the audience. The staff confined their comments to answering questions, except when they spoke as a professional. At such times they indicated that they were speaking as professionals and not as members of the OAB staff. Comments received at the meetings and from subsequent meeting evaluations indicate that the informal meeting procedure used was well received and led to good, non-confrontational open discussion and participation.

These points are the condensation of the five public meetings summarized by Gerber, Robinson and Phillips.

Public Meetings-Analysis of Attendees Organizations or Affiliations				
Category			Number	Percent
University Researcher			25	22
University Administrator			3	3
IBC Member			13	12
Industry			18	16
Trade Association			2	2
Special Interest Group/Organization			6	5
State Agency			4	4
ABRAC[1]			8	7
News Media			5	4
Federal Agencies				
	USDA		1	1
		CSRS	2	2
		ARS	1	1
		APHIS	3	3
		ERS	2	2
		FS	1	1
		FSIS	1	1
	FDA		1	1
	NIH		1	1
	NOAA/ NMFS		3	3
	GAO		1	1
	EPA		3	3
	OTA		1	1
International			6	5
Totals			111	

[1]May also be University Researcher/Adminstrator.

Public Meetings- Analysis of Location of Attendees	
California	16
Wyoming	3
Utah	1
Iowa	4
Oklahoma	1
Washington, DC	19
Arkansas	2
Illinois	5
Missouri	2
Maryland	7
North Carolina	11
New York	2
Nebraska	1
Kansas	1
New Jersey	1
South Dakota	1
Connecticut	1
Virginia	1
Georgia	1
Mississippi	1
Alabama	1
Florida	1
Ohio	1
New Mexico	1
Great Britain	2
France	1
Sweden	1
Canada	1
New Zealand	1
23 States + D.C., 6 Countries	85 U.S. + 6 Foreign

Comments From Public Meetings
On Guidelines

Sacramento, CA
September 17, 1990

1. What is the role of Institutional Biosafety Committees (IBCs) in providing assurance of safety for field research? Will they be expected to review confinement protocols?

2. Will the IBCs be expected to review the environmental analysis?

3. IBCs need a national standard for format and procedures for review of proposals for field research to be submitted to USDA for funding. Need a flow chart especially at the onset of the implementation of the guidelines.

4. Principal investigators (PIs) need a standard format to be used to prepare NEPA documents.

5. Is funding dependent upon use of the guidelines?

6. To what extent would private industry be expected to follow the guidelines?

7. Are we overburdening the scientific community with more paper work?

8. How does the researcher decide to follow APHIS, EPA or the USDA guidelines?

9. There is a need for a coordination or clearing house to avoid the problem of overlapping jurisdiction. This problem needs resolution and a flow chart developed.

10. The guidelines would be very helpful to the researcher in the design of a field experiment, even if permits were to be issued by APHIS or EPA.

11. There are no guidelines for preparing a request for a permit from APHIS. OAB could help by being a clearing house to direct applications to responsible agency and by developing some guidance for investigators.

12. USDA should make sure that there guidelines expedite not obstruct field research.

13. With respect to animals, there are no guidelines for applying to APHIS for a permit to test vaccines. Guidelines

would make it much easier for an investigator to decide what to do.

14. The Scope definition is not clear.

15. The guidelines should be made into a handbook for the investigators.

16. There are overlapping jurisdictions and the IBCs should be trained so that they can assist investigators in determining which agency has jurisdiction.

17. Don't have any misleading terms. Include a list of all organisms which must be confined.

18. Low risk research should be approved quickly. Concentrate efforts on high risk field research.

19. The guidelines should include a mechanism to exempt certain organisms or types of field research in the future.

20. It is urgently important to the universities that the guidelines are published and adopted quickly.

21. Private industry is not well informed about the guidelines.

22. USDA should develop a list of organisms which are generally considered to be safe for field research.

23. The guidelines do not address the interstate shipment of organisms or constructs. This may be important to the development of field research.

24. The definition of release or introduction into the environment needs to be carefully defined for field research to provide clear distinctions between field research and commercial release.

25. The guidelines should make it clear that introduction into a confined environment is not release into the environment. Avoid any indication that guidelines apply to open commercial release.

26. How does USDA meet NEPA requirements for classical field research? How will USDA use guidelines to comply with NEPA and how does the public get involved?

27. Will the guidelines apply to field research funded by federal agencies not a part of USDA?

28. The guidelines do not indicate any interagency cooperation for field research.

29. While industry has not followed these guidelines carefully, they will study them closely. Generally it is essential that industry have public support and industry will do whatever is necessary to gain and keep that support. They do not want to give any impressions that they wish to circumvent or short circuit any responsibility or prudence.

30 Parental organisms need to be more carefully defined.

St. Louis
8:00 a.m.
September 19, 1990

1. APHIS filed testing permits are very satisfactory for some universities field testing.

2. What do guidelines mean in terms of extra paper work for the individual PI preparing a proposal?

3. Need a flow chart for the guidelines and assurances that the same mechanism is available to both industry and universities.

4. Procedures should be the same for the universities and industry. There should not be a double standard.

5. Consortia have been formed between universities, government and industry. These consortia must have a single, simple procedure for field research.

6. There is such a massive wall of regulations (EPA, APHIS, NEPA) that many investigators are avoiding field research.

7. Will it be required to follow the guidelines in order to get funding of proposals from USDA?

8. Universities may view the guidelines as something to be overcome and therefore could inhibit field testing. However, if the guidelines help educate investigators on how to do field testing they may be worthwhile.

7. Unifying the requirements for field research for all agencies would be highly desirable.

8. Can there be one standard set of guidelines for all field research not just for USDA?

9. Separate field research from field product development research.

10. Don't make overlapping requirements for field research.

11. Universities and industry are common providers on information and should follow the same guidelines.

12. Don't understand why there is a desire or need to determine the safety level of existing organisms.

13. There has not been uniform acceptance of the scientific aspects of the guidelines.

14. Will the guidelines apply to the release of non-genetically modified organisms? What is being done about the environmental impact of all field research?

15. Will guidelines apply to field research with organisms for which there will never be any commercial release. Proof of scientific concepts and principles, etc.

16. The guidelines don't address the socioeconomic issues raised by field research with genetically modified organisms.

17. The public expects the federal government to ensure safety and protect the public in all field research, not just that funded by USDA.

18. Federal oversight of the IBCs, coupled with peer review, might help ensure public safety and remove some potential problems of local pressures on IBCs to approve specific proposals.

St. Louis
1:30 p.m.
September 19, 1990

1. Definitions of organisms is not clear.

2. Why are there so many exclusions? Is USDA trying to exclude classical means of plant and animal breeding and microbial strain improvement? Definition is too vague and subject to manipulation. It is hard to tell what is included and what is excluded.

3. Scope definition is not clear with respect to chemical mutagens.

4. How are agencies making decisions on what to examine? Is it clear that USDA will not regulate solely on the basis of being genetically modified?

5. Functional and public perceptions of regulations are that they are based on process (rDNA), not product.

6. All that anyone is interested in are biotechnologically

altered organisms.

7. How does one define "risky" organisms?

8. One can't isolate process and risk.

9. IBCs need a step-wise administrative procedure to show how process of approval functions. Need a flow chart.

10. Coordination is need to assure that there is not double oversight.

11. NEPA requirements for research are not clearly articulated or understood.

12. USDA should decide on a "case-by-case" basis, rather than on a generic classification, of which organisms require oversight.

13. What are the NEPA requirements for classical research?

14. How will categorical exclusions be determined?

15. What will they be and when will the requirements for commercialization be completed?

16. Will there be memos of understanding between ARS, CSRS, FS, APHIS and EPA on environmental analysis?

17. Why has USDA put so much emphasis on regulating research rather than on expediting research?

18. Is there any written documentation on agency interactions?

19. The guidelines should be entitled "Guidelines for Research Being Done in the Field", rather than just on generic research.

20. The IBCs biosafety officers need guidelines, because field research is the logical outgrowth of research conducted in contained facilities under the NIH/RAC guidelines. NIH is behind on appendices "P" and "Q". The guidelines are needed for accessing the biosafety of projects and allowing the research to be finished in the field.

21. There is a need by the universities for the guidelines now.

22. APHIS, EPA requirements and the Guidelines need to be integrated or at least combined into one document.

23. Put NBIAP on a national network (Dialog, Orbit, STM).

24. The guidelines should be for introducing and extending rDNA research into the field.

25. Change the title to " The Environmental Impact of Planned Introductions into the Defined Environment of Organisms with Deliberately Modified Hereditary Traits."

26. How do the guidelines relate to EPA and APHIS guidelines and how are they coordinated?

27. If the Omnibus Biotechnology Bill is passed what impact will it have on the guidelines?

28. The confinement protocols and the safety concerns need to be limited to the defined environment (confinement).

29. Specify in some detail and layout confinement levels to handle risk.

30. Define and/or construct a series of scenarios on how to determine the risk and design an appropriate confinement.

31. The guidelines could have an educational value for the IBCs and PIs.

32. There is a need for a public education program on field research and safety.

33. Have a workshop(s) for IBCs as soon as guidelines are finalized and adopted.

34. There is a need for public education on oversight.

35. Does the fact that organisms can be patented produce apprehension in the public mind?

36. IBCs should be able to say "If we follow the guidelines, then the research is as safe as it can or need be".

37. Guidelines should allow a risk/benefit analysis that provides opportunities to perform high risk/high benefit research.

38. Does injection of an animal with a recombinant product constitute research with a deliberately modified organisms?

39. Guidelines need to address risk management and steps to take if confinement fails.

40. Try to make the public more aware of the depth of oversight of the research.

Raleigh Meeting
September 21, 1990

1. The sequence of events which motivated these meetings are the discovery of rDNA, it's use in contained lab facilities, the extension of the resultant organisms into the field research, and the eventual commercialization based upon the field results.

2. Are the guidelines only for research, or are they intended to apply to commercial companies?

3. Do the guidelines apply if one uses only state or private funds to conduct the research?

4. If the private companies follow the guidelines will it expedite their ability to go to the field? Will it streamline the process?

5. The major issue for industry is commercialization and the development of guidelines for this.

6. Universities agree with the need for the guidelines, but confinement costs are too high, especially for animal research.(BSL-3)

7. The universities are not prepared to do the legal work necessary to obtain field permits from APHIS and EPA. They are barely able to do the work necessary for patent protection.

8. Universities are spending their legal resources pest/pathogen work and on plant variety protection.

9. There may be serious problems from mixed funding between the universities and industry.

10. To make the guidelines really work there needs to be a provision to go beyond field research to commercialization.

11. The universities are worried about public challenges on legal, social, and ethical basis related to biotechnology.

12. Build public confidence by providing an oversight mechanisms for safety. To do this the guidelines need to be in place as soon as possible.

13. Science is lagging in the U.S. and Europe is gaining or ahead of the U.S. because we don't have guidelines.

14. Biotechnology is not being integrated into field research.

15. There is a structural failure in the way field research is being done. Universities are being excluded from linkages with industry by APHIS issuing most field permits to industry.

16. Environmental groups can be influenced by involving national leadership who can and will allay members and public fears about field research.

17. Guidelines and BSCC seem to be preoccupied with risk and not influenced by considerations of benefits.

18. Need to pay close attention to cost/benefit analysis. USDA seems to be trying to achieve zero risk.

19. Many biotechnologies have environmental benefits, these should be emphasized.

20. NEPA includes cost/benefit analysis and displays it.

21. Goals of guidelines should be to achieve reasonable risk. Reasonable risk needs to be defined.

22. Using biotechnology to decrease damage to the environment should be reflected in the guidelines.

23. Need a standard format for environmental analysis.

24. Low risk/high benefit field research should be pushed through quickly.

25. The guidelines as initially conceived were thought to not be possible. What has emerged is a set of open principles and not a closed "Black Box" case-by-case process.

26. Either the IBCs or OAB could help by explaining the process of use of the guidelines for field research proposals.

27. There is need for a document to explain IBC roles and responsibilities and what they do in reviewing research for the USDA agencies.

28. The definition of the role of the ABRAC needs to be improved.

29. If more demands are made on the IBCs they will accept it, but they need training.

30. Who is responsible for preparing NEPA analysis?

31. Will submission of a NEPA document for the federal agency meet state needs?

32. APHIS uses PIs directly and does not involve IBCs.

33. There needs to be a well defined provision for public review of proposals to do field research.

34. State and federal categorical exclusions need to be aligned.

35. IBCs should be constituted to have expertise as specified by USDA, and a process established for OAB to review composition of IBCs.

36. A condensed brochure for policy makers will be needed when the guidelines are finalized.

37. There should be a safety impact assessment rather than an environmental analysis.

38. An analysis of the level of safety concern of the modified organisms should be included.

39. There is less concern about the content of the guidelines than about the need for a rapid adoption of them.

40. Field results will provide the basis for development of a list of modified organisms that are safe to use in the field.

Washington, DC
September 26,1990
9:00 a.m.

1. A formal statement was made by Jane Rissler, on behalf of the National Wildlife Federation. Copies of this statement are available upon request.

Points from the informal meetig were:

1. There are no incentives or enforcement of the guidelines. Perhaps the guidelines in there present form should be withdrawn and a draft prepared that protects human health and environment and provides for meaningful public participation.

2. How can the guidelines be used for NEPA?

3. Clarify the relation between the NIH and USDA guidelines. NIH used an EIS to demonstrate the adequacy of containment. Will the USDA do the same for confinement?

4. How can USDA use the RAC IBCs to evaluate field research?

5. There needs to be cooperation and coordination between federal agencies on field research. This should probably take the form of interagency agreements.

6. How far from the resolution of guidelines issues is the USDA?

7. There is additional public involvement needed, which should be specified in the guidelines.

8. Proposed guidelines should provide oversight.

9. Withdraw the draft guidelines and publish a new policy open to public participation, with an EIS.

10. Other agencies need to be actively involved with OAB and ABRAC in developing the guidelines.

11. There is a need for oversight and training of the IBCs when the guidelines are completed and implemented.

12. The biggest problem the IBCs face is not knowing what the agency expectations are. The agencies should provide this information to the IBCs.

13. Deliberately modified is not clearly defined. Exclusion 5 is confusing.

14. Processes in the guidelines has been lost. A flow chart of procedure is needed.

15. IBC's need to have federal oversight.

16. Guidelines relate to biosafety only, not environmental impact.

17. State and federal guidelines should be in agreement.

18. The final exclusions in the guidelines is too big a loophole. It needs to be defined more carefully and explained better.

19. The guidelines are a part of a larger process and should not be viewed alone.

20. The States are working on guidelines, as well as OECD. How do the USDA guidelines relate to these documents?

21. There is a need for the agencies to coordinate in training the IBCs and to prioritize their efforts.

22. There is a need to improve the quality and training of the IBCs.

23. Organized training of the IBCs is needed. This training based upon NIH experience can not be done on an ad hoc basis, but must be a series of coordinated sessions to bring everyone to a common level of understanding.

24. IBCs need instruction in appropriate public involvement.

25. Is the scientific basis of the scope exclusions well accepted?

26. Inform the public on what the USDA will do to implement the guidelines. Improve the preamble. Where does OAB intend to go?

27. Look at how other agencies have incorporated cost/benefit in NEPA documents and use a similar approach.

28. Provide examples of modified organisms, not just parental organisms. The examples which are given help, but could be expanded.

29. Field experiments could result in a list of biosafety results incorporated into a data base which could be added to examples in appendix.

30. Most researchers want to see guidelines published now, so they will know what is required for field research.

31. There should be some consideration to having state-wide IBCs and sharing costs and obtaining a greater range of expertise.

32. The guidelines are a hybrid with NEPA.

33. With some reservations the guidelines may be adequate.

34. There is not adequate provision for public involvement in the guidelines.

35. Questions USDA's competence to design the guidelines.

36. The public meetings do not constitute meaningful public participation.

Oklahoma State University

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July 20, 1990

Dr. Bennie I. Osborne
Department of Veterinary Pathology
School of Veterinary Medicine
University of California
Davis, CA 95616

Dear Dr. Osborne:

At our most recent NASULGC Committee on Biotechnology meeting (Washington, D.C., June 28, 1990) the discussion turned to mechanisms for the deregulation of those aspects of biotechnology research known to be safe. Such mechanisms to deregulate biotechnology are in place but require preparation and submission of a petition to the appropriate Federal agency. As an example, I cite the provisions under 7 CFR 340 (the APHIS Plant Pest regulations as applied to biotechnology).

It was noted during our discussion that no organized constituency has emerged to undertake this function. ABRAC was suggested as a likely body to serve this function. Our committee would like you, as chairman of ABRAC, to give us your evaluation of this proposed function. Additionally, do you feel that there are other, more appropriate petitioners for deregulations?

Thank you for considering this request.

Sincerely yours,

C. B. Browning
Dean and Director

sdl

cc: Biotechnology Committee

United States Department of Agriculture

Office of Agricultural Biotechnology

Administration Building
Room 321-A
Washington, D.C.
20250-2200
(202)447-9165

November 1, 1990

MEMORANDUM

TO: Alvin Young

FROM: William M. Robinson

SUBJECT: Conflicts of Interest for ABRAC Operational Procedures

In the enclosure I define conflicts of interest, describe the purpose of having a policy on this issue, and propose a disclosure requirement to incorporate in the OPERATIONAL PROCEDURES FOR THE AGRICULTURAL BIOTECHNOLOGY RESEARCH COMMITTEE.

I claim no special expertise in the area of ethics and conflicts of interest, other than standard public administration education and an intuitive understanding gained from over three decades of public service. Much of the draft is simply what I think of as "common sense" about ethics of public service. The "Conflicts of Interest in Biomedical and Biotechnbology Research" Conference in Boston helped sharpen my thinking and suggested some of the language I used. I am sure that a rigorous staff review will improve my draft and will result in a policy proposal you will be comfortable distributing to ABRAC.

William M Robinson

ETHICS, CONFLICTS OF INTEREST, AND THE ADVISORY COMMITTEE

Conflict of interest is defined for puposes of these Operational Procedures as a circumstance where a person is unable to give the government impartial help or advice because of other activities or relationships, or where someone is given an unfair competitive advantage because of special knowledge or information gained as a result of serving on the advisory committee.

The basic purpose of conflict of interest policy is to ensure objectivity and unbiased judgements on various issues the ABRAC members are asked to examine. USDA and the public want to be assured that "scientists and administrators don't have their fingers on the scale" someplace, and that safety of biotechnology research is uncompromised.

The focus of the policy is to require the least intrusive disclosure of personal or institutional interest in an issue that is sufficient to achieve the basic purpose. To fulfill these needs, members (and future nominees) will be asked to disclose the following interests in organizations whose research or product is subject to reviews, evaluations, recommendations, and/or actions brought before the committee:

- service as officer, director, trustee, partner or employee of such an organization;
- negotiations with or arrangements concerning prospective employment with such an organization;
- and financial interests and funding (such as support for lab activities, special equipment, services, consultancies and honoraria) from such an organization.

The information will be updated annually and kept for two years. Changes in the information should be disclosed as soon as possible and not held until the annual updating.

Financial holdings, research interests, or participation in a project or activity won't automatically bar members from participating in such cases that come before the committee; however, a review panel of USDA and ABRAC representatives could be formed to back up the findings of members who have such ties.

THE MILLS HOUSE HOTEL
A HOLIDAY INN® HOTEL

November 27, 1990

Dr. Charles Hess
Assistant Secretary
Science and Education
Department of Agriculture
Washington, D.C. 20250

Dear Secretary Hess:

At the meeting of the Agricultural Biotechnology Research Advisory Committee (ABRAC) on November 25-27, 1990, the events that have transpired regarding your actions on the ABRAC-developed Guidelines were presented to the Committee and discussed. The attached resolution was developed and unanimously passed by the members present. We sincerely wish you success in your efforts and hope that this expression of ABRAC's support conveys our continued support.

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RESOLUTION

WHEREAS, the agricultural research community is in need of guidance to proceed with field testing of genetically modified organisms, and

WHEREAS, the Agricultural Biotechnology Research Advisory Committee (ABRAC) has developed a functional set of guidelines for "Research Involving the Planned Introductions Into The Environment of Organisms with Deliberately Modified Hereditary Traits", and

WHEREAS, the recent public meetings held by the Office of Agricultural Biotechnology (OAB) confirmed the urgent need for these guidelines,

THEREFORE, let it be resolved that ABRAC supports and is appreciative of efforts by Assistant Secretary Charles Hess in moving through the complex governmental steps required for approval and publication of the principles in the ABRAC Guidelines in the Federal Register.

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